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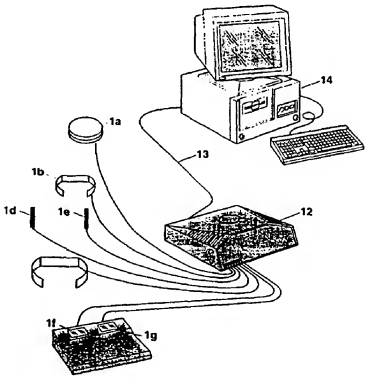
(54) Title: ELECTRO-MEDICAL APPARATUS

(57) Abstract

An electro-medical apparatus comprises at least seventeen electrodes (1a-1g), which are applied on some specific areas of the human body of a patient for receiving bio-electrical signals; said signals are automatically processed by means (13, 14, 16), so that the software of a personal computer (14) could analyze the health state of the patient. In addition, an "expert system", which comprises a control software, an analysis software and an interpretation software, provides the physician with first indication data about the health of the patient and with possible modes of intervention, so that the physician could arrive to a substantially definitive interpretation of the health state of the patient.



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Electro-medical apparatus

The present invention relates to an electro-medical apparatus comprising a plurality of electrodes, which are adapted to receive bio-electrical signals emitted by an individual, in correspondence of specific areas of his body and comprising means for collecting data collected by the electrodes, so that said signals could be analyzed and a substantially objective evaluation of the equilibrium of the body fonctions at the level of said specific areas could be performed.

Since some tens of years engineers posed the problem to make easier the analysis and the diagnosis of the human body fonctions as well as to help physicians in the objective evaluation of the patient's health.

It is since about twenty years that German physicians would have been able to acquire the bio-electrical signals, which are emitted in correspondence of specific areas of the human body, and so they obtained from these data bio-electrical information of an individual, who is examined by a physician. It is well known that the human body emits electrical signals in correspondence of its specific areas. Said signals, duly picked-up and amplified, allow to translate the signals (microampere, microvolt, ohm, conductance, frequency, etc.) into data, which are related to the more or less normal equilibirum of the examinated individual.

The first apparatuses, which were conceived in Germany, would analyze the bio-electrical state of seven areas of the human body, as well as proceed in the reading of the electrical potential, stimulate the measure area with a 10 Hz. impulse package in order to remeasure the conduttance in that area, to make the passive reading of the (inverse) current discharge, stimulate again the measure area with an inverted current impulses, read again the value of said current and therefore of the electrical potential. Said current was repeated seven times on seven human body areas.

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The information, which was collected from the seven analyzed areas, had to to be evaluated according to a substantially objective way from the physician, who had used the bio-medical apparatus. The important fact was made of the method, which allowed to use the bio-electronic information and allowed to make a diagnostic interpretation. Already at the time the collected information should be based on a statistic interpretation, but it was recognized that this infonnation would prove the normality or the abnormality of a certain area of the body, for instance the patient's head.

It should be pointed out che the cletromedical apparatuses, which were born in Germany, were able to give the physician a series of data, which were then translated into graphics. These graphics were rather difficult to decipher, whereby at least some years were necessary to the physician in order to fairness interpret these data.

The German manufacturers of said apparatuses arrived to a considerable sophistication as far as the electrical data meausure in some human body areas is concerned, as well as to involve acupuncture therapies, Chinese medicine, etc. But they limited themselves to substantially decode the electrical data of these measures and to simplify their interpretation.

In the U.S.A. the analysis technique of electrical potentials mainly as encephalograms, sleep state measurement, and so on., but not as bio-functional measures. i.c. the measures, which provide elements for arriving to a certain diagnosis and to say, on the collected data basis, whether a certain orghan of the human body is working or not and how much this working is moving from a normal state.

Meanwhile it is to be pointed out that said bio-functional measures present a further important advantage, i.e. they can record according to a specific way the health state of an individual and a further analysis, which confirm the same data, should just correspond to the same individual and never to another one.

As for Japan, they just started to develop a similar apparatus and we would likely learn quite soon interesting news in the field of the bio-electronic.

The German school of the bio-functional measures just arrived up to indicate the electrical signals (conductance, current, etc.), which are present in correspondence of specific areas of the human body and arrived to suggest, by comparison and by survey, a rather reduced

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interpretation of the collected data meaning. It could be a further big success for the producers of such a apparatus to
use it after a less long time, which is requested for a good training even with the help of a data bank.

Not only the Italian physicians, who use a scientific apparatus, require that the same apparatus should give the elements of a certain result, i.e. of a certain diagnosis, whereas the same physicians intend to arrive to definitive diagnostic conclusions. Therefore, what is important not only in Italy is the apparatus could supply a certain outline, whereas the physician should verify the outline which is given by the apparatus.

On the basis of the collected data, which are not subjected in Germany to particular processing or decoding, further measures could suggest the physician the possible patient change of state, whereby the most critical point depends on the results of the first examination, because it is much easier to make a comparison of the data collected later on with the data previously collected.

In order to summarize what up to now was explained, the similar German apparatuses provide data, which are often subject to a difficult, subjective interpretation, whereby a risk is present in the possibility of errors in such an interpretation.

As for the safety of these apparatuses, the German ones are generally working with a power supply of 220 V. 50 Hz., which could affect the patient state and the response of the apparatus. In the field of the bio-electronics the energy supply should be substantially insulated. The signal, which is emitted by the apparatuses, should be quite clean, whereas the German ones don't respect such a requirement because they were conceived about 20 years ago, when the microelectronics was not in the condition to give substantially better resolutions.
The interpretation of the tests, which were carried out by the German apparatuses, was depending on the diagram plotted on a sheet of paper, with no reference to digital values for a rather quantitative interpretation of the data.

The main problem, which the apparatus according to the invention intends to solve, is to to propose an instrument of the bio-energetical-functional type, which should be able to evaluate wheher and to which extent the various organs or systems of the patient are working or not.

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how much they are moving away from the optimum conditions, which one could be the origin of the problem and, at last, how to make the patient prevent from the deviation.

It should be observed that at least two different schools are present in the medical field: the first one is belonging to the classic school, which suggests after ascertaining the presence of a disease to intervene in order to eliminate the disease. The bio-energetical-functional school does trouble to establish the presence of an abnormal state, but mainly it does trouble how much the present state of the patient is moving away from a normal state, as well as when and according to which extent the patient is moving up again during and after a therapy. The bio-electronical science intends to make prevention and to monitor the therapy through a well-timed and continuous control of the evolutive and involutive patient state.

This problem is solved by the apparatus according to the invention, which is characterized by at least seventeen areas of the human body on which the electrodes are able tol operate through the data collection, in order to confine substantially narrower human body areas and consequently di increase the passage tracks of the collected information, means being provided for a substantially automated processing of the collected data.

A further goal the apparatus according to the invention intends to reach is to decode within real times and according to substantially reliable way the bio-electrical information collected by the apparatus as to help the physician by providing him substantially more detailed data.

This problem is solved by the apparatus according to the invention, which is characaterized in that it is able to substantially decode and to process all the bio-electrical information which are provided by the electrodes and to present them according to a digital shape, so that the software of the PC could analyze the health state of the patient by leaving aside the necessity of graphs, charts and similar.

A last problem that the apparatus according to the invention intends to solve is given by the opportunity to analyze organ by organ of the patient the situation of his health state, by comparing any specific situation with a series of data statistically collected from a data bank, so that the physician could evaluate the criticality of a certain situation, said situation being able to be connected with other specific situations or not.

Said problem is solved by the aparatus according to the invention, which is characterized by at least an "expert system" which comprises at least a control software adapted to control the

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same apparatus, a analysis software adapted to decode the electrical information collected from the various areas of the body and to translate them into graphs and an interpretation software adapted to provide the physician with first indication data about the health state of the patient and with possible modes of intervention, in order the physician is allowed to arrive to a substantially definitive interpretation of the health state of the patient.

Said and further features of the invention will be apparent from the following description and from the alleged drawings, where:
Fig.1 represents a schematic perspective view of the apparatus according to the invention;
Fig.2 represents a sample of bipolar graph processed by the apparatus;
Fig.3 represents a humanoid provided with the areas which were subjected to reading.

The apparatus according to the invention comprises a plurality of electrodes 1a,1b,1c.1d,1e,1f,1g which are adapted to be applied in various areas of a human body of Fig.2 (3=right arm, 4=the right part of pelvis, 5= the right leg, &= the head, 11= the left leg). The electrode 1a is to be applied to the head, the electrodes 1b,1c are to be applied to the arms and to the legs, respectively right and left, the electrodes 1d,1e to the respectively right and left body parts, the electrodes 1f,1g to the respectively right and left foot.

The electrical signals of the various body areas are collected by a hardware 12, which as it will be apparent later on the signals are addressed to the software of a PC 14 so that they can processed and reported on a bipolar graph 16 (Fig.2). In such a graph the data are processed by the PC, are separated according to each examined area (the areas are seventeen) along the abscissa, whereas the ordinate represents the positive and negative values for each examined area. The positive values represent over-values and the negative values the under-values.

The apparatus according to the invention operates according to the following way.
- the values of the electrical tension are detected in correspondence of the seventeen areas of the human body, whereby the relevant situation of these areas is stored in the hardware 12;
- later the various areas are stimulated with a low electrical tension 13 Hz.; the response is recorded;
- at first the feet of the patient are involved, which are put on the electrodes 1f,1g. In such a way the organism is excited in order to brig the patient to an active bio-electrical level. Thanks to the low electrical tension 13 Hz., the patient could become diagnosable. Indeed the patient's conditions vary hour by hour during the day, whereby the reading of the detected values could substantially vary during the day. In Germany the patient is subjec-

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ted to a shock from temperature or from pain;
- the feet are subjected to a positive and then negative value of the electrical tension, in order to depolarize the excited area, during 13 sec.

The graph of Fig.2 reveals the maximum bio-energetical over-alteration in correspondence of the areas 3,6,11, whereas it reveals the minimum bio-energetical under-alteration ion correspondence of the areas 4,5. The circles A,B of the humanoid represent respectively the two detected areas as abnormal areas.

The described apparatus is also able to provide samples of uni-polar graphs, which are not represented in the drawings. In addition the hardware 12 should be controlled by and should be directly depending on the PC 14, which practically is not autonomous. Indeed also the hardware 12 is internally provided of a software, which is not represented in the drawings. The hardware 12 and the PC 14 are able to dialogue each one with the other through the interface in the hardware 12. For instance if a value of electrical tension is read in the area 1 (Fig.2), this value is read and stored in the hardware 12, which is transducted into a digital language in order to send it to the PC.

The logical sequence of the process practically provides the following phases:
- all the values of electrical tension of the various areas are detected and stored into the hardware 12;
- the patient is stimulated in correspondence of his feet with a low electrical tension 13 Hz. so that the test could become objective after the patient has obtained substantially optimum bio-electrical condition;
- in correspondence of each one of the seventeen areas a stimulus is emitted and the reply is stored as a whole for one first and a second time;
- after stored all the digital information, such an information is stored in a so-called "expert system" which analyzes the digital data. Such an analysis is carried out by said "system" for a comparison with the statistical data, which were collected during the last 20 years, and which allow to ascertain whether the digital data are comprisedm into the ranges or not. Such an "expert system" comprises at least a control software, which controls the hardware 12, an analysis software, which decodes the electrical information collected in the various areas of the body and represents them in mono- or bi-polar graphs, and at last an interpretation software, which provides the physician a first indication of the patient health state. Such a software practically represents the software of the PC 14;
- the PC processes the mono- or bi-polar graphs, so that the areas, which are affected

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by a bio-energectical-functional excess or lack;

- the information, which are represented by the test data, allow to process the diagrams for the interpretation of the various parameters obtained in correspondence of the seventeen areas (oxygen, PH, functional blocks, energetical level, inflamation level, toxin presence, chronicity level in correspondence of the various measure levels, etc.).

In conclusion the apparatus according to the invention allows thanks to the hardware 12 the automatic processing od the collected data, and avoids the risk of a subjective interpretation, for istance the interprctation carried out with the German similar apparatuses, which are providing plotted graphs on paper sheets.

Also the safety is ensured because the power supply 220 V. 50 Hz. is eliminated, which can negatively affect the health state of the patient and the working of the apparatus, which can now work thanks to a power supply made of 12V. batteries. In such a way, the data collection and processing, as well as the test quality are ensured.

At last, the apparatus according to the invention provides a bio-energetical-functional instrument, which can verify whether and according to which extent the various organs or apparatuses of the patient are well working or not, and how much this working is moving from optimum conditions, which one could be the origin of the problem and how to make the patient prevent from the deviation.

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C L A I M S

1. Electro-medical apparatus comprising a plurality of electrodes (1a-1g), which are adapted to receive bio-electrical signals emitted by an individual in correspondence of specific areas of his body and comprising means (12) for collecting data collected by the electrodes, so that said signals could be analyzed and a substantially objective evaluation of the equilibrium of the body functions at the level of said specific areas could be performed, characterized by at least seventeen areas of the human body on which the electrodes (1a-1g) are adapted to operate through the data collection, in order to confine substantially narrower human body areas and consequently to increase the passages tracks of the collected information, means (13,14,16) being provided for a substantially automated processing of the collected data.

2. Apparatus according to Claims 1,2, characterized in that it is able to to substantially decode and to process all the bio-electrical information which are provided by the electrodes and to present them according to a digital shape, so that the sofware of the PC (14) could analyze the health state of the patient bny leaving aside the necessity of graphs, charts and similar.

3. Apparatus according to Claims 1,2, characterized by at least an "expert system", which comprises at least a control software adapted to control said apparatus, an analysis software adapted to decode the electrical information collected from the various areas of the body and to translate them into mono- or bi-polar graphs (16) and an interpretation software adapted to provide the physician with first indication data about the health state of the patient and with possible modes of intervention, so that the physician is allowed to arrive to a substantially definitive interpretation of the health state of the patient.

4. Apparatus according to the preceeding Claims, characterized in that the hardware (12) is controlled by (and is directly depending on) the PC (14), which is adapted to dialogue with the hardware (12) through the interface in the hardware (12), so that the reading of an electrical tension through an electrode (1a-1g) applied on the body of the patient can be carried out, stored in the hardware (12) and then transducted into a digital language up to the PC (14).

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5. Process of apparatus claimed in the Claims 1-4, in order to put a physician to perform a substantially objective and reliable diagnosis of a patient, characterized in that it comprises the following phases:

- the values of the electrical tension in correspondence of seventeen areas of the organism are detected and stored in the hardware (12);
- each one of the seventeen areas is stimulated with a substantially low (not higher than 5 V.) electrical tension 13 Hz. and the reply is stored into the hardware (12);
- the process starts by stimulating the feet of the patient, which are put on the electrodes (1f,1g) in order to ensure that the patient is active at a bio-electrical level, so that objective values of the test could be obtained;
- the feet are subjected to a positive and to a negative value of electrical tension, in order to depolarize the excited areas during 13 sec.;
- the values of the electrical tensions of the various areas are acquired and are stored in the hardware (12);
- in correspondence of each one of the seventeen areas an electric stimulation is transmitted and the reply is stored at a whole;
- after obtaining the digital information, the "expert system" analyze the relevant digital data and compares them with with the statistical data of the last 20 years, so it is possible to ascertain whether these data are comprised or not into the ranges;
- the PC (14) processes the mono- or bi-polar graphs and ascertains which areas are affected by a bio.energetic-functional excess or lack or which areas are comprised into said ranges;
- thanks to collected and processed information, the mono- or bi-polar graphs are allowed to interpret the parameters of the various explored areas, said parameters being adapted to comprise: oxygen, PH, functional block, energetic level, inflammation level, toxyn presence, chronicity level in correspondence of the various measure levels, etc..

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all this in order to allow an automatic processing of the collected data and to avoid the risk of a subjective interpretation, for instance the interpretation carried out with the German similar apparatuses, which are providing plotted graphs on paper sheets, said graphs being of a substantially difficult interpretation, which require at least some years of experience. In addition a bio-energetic-functional analysis is allowed, with the aim to evaluate whether and according to which extent the various organs or apparatuses of the patient are well working ot not and how much said working is moving from optimum conditions, which one could be the origin of the problem and how to make the patient prevent from the deviation.

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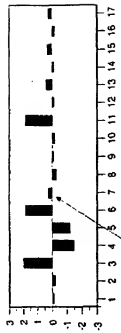

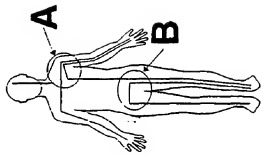

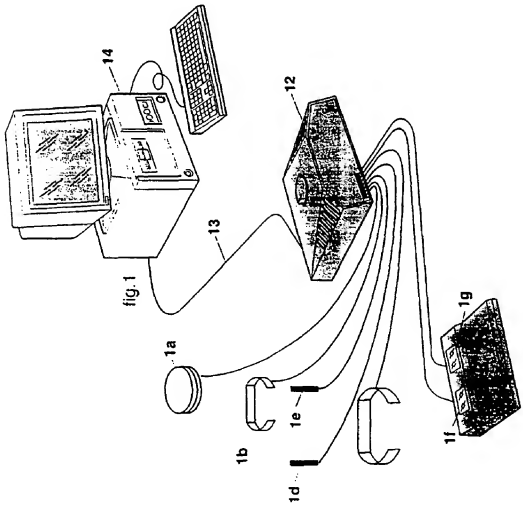

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INTERNATIONAL SEARCH REPORT

Interna al Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B5/05

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95 02360 A (SARID) 26 January 1995 see page 8, line 8 - page 11, line 4 see page 15, line 1 - page 16, line 22 see page 18, line 19 - page 20, line 9 ---	1-3
X	AU 594 573 A (JAHNKE BIOELEKTRONIK) 8 March 1990	1
Y	see page 1A, line 1 - page 2, line 29 see page 4, line 1 - page 6, line 25 see page 9, line 1 - page 11, line 6 see page 15, line 26 - page 16, line 21 --- -/--	3,5

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	FR 2 676 930 A (N. PEKARIC-NAD) 4 December 1992	3,5
A	see page 2, line 8 - page 3, line 4 see page 5, line 28 - page 6, line 8 see page 8, line 8 - line 10 see page 10, line 24 - line 33 see page 17, line 1 - line 37	1,2,4
P,A	WO 97 01303 A (K.C. CHA) 16 January 1997 see page 4, line 25 - page 7, line 4 see page 8, line 8 - page 9, line 27	1,5

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Interna... Application No
PCT/IT 97/00118

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